REMARKS

Claims 78-101 are pending in the application. Claims 78-86, 89-90 and 96-97 have been withdrawn from consideration by the Examiner. The remaining claims, i.e., nos. 87-88, 91-95 and 98-101 are subject to restriction and/or an election requirement. Claims 98-101 have been amended to correct their dependency. As amended, these claims now depend from claim 96. The amendment was deemed necessary to provide an appropriate antecedent basis for the phrase "the portion" in the subject claims. The amendment does not raise any issue of new matter.

The Examiner requires restriction to one of the following inventions under 35 U.S.C. §121:

I. Claims 87-88, 91-95 and 98-101, drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA14, PA8, PA9, PA10, PA11 "and" PA12, classified in Class 536, subclass 23.53.

II. Claims 87-88, 91-95 and 98-101, drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA14, classified in class 536, subclass 23.53.

III. Claims 87-88, 91-95 and 98-101, drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA8, classified in class 536, subclass 23.53.

IV. Claims 87-88, 91-95 and 98-101, drawn to a nucleic acid molecule that encodes one or more CDR regions

of an anti-CCR5 monoclonal antibody designated as PA9, classified in class 536, subclass 23.53.

V. Claims 87-88, 91-95 and 98-101 drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA10, classified in class 536, subclass 23.53.

VI. Claims 87-88, 91-95 and 98-101 drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA11, classified in class 536, subclass 23.53.

VII. Claims 87-88, 91-95 and 98-101 drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA12, classified in class 536, subclass 23.53.

The Examiner stated that the inventions are distinct, each from the other and that inventions I and II-VII are related as combination and sub-combination. The Examiner stated that inventions in this relation are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the sub-combination as claimed for patentability, and (2) that the sub-combination has utility by itself or in other combinations (MPEP §806.05(c)). The Examiner stated that in the instant case, the combination as claimed does not require the particulars of the sub-combination as claimed because not all sub-combination, nucleic acid molecules that are drawn to different antibodies are necessary to produce the combination, a nucleic acid molecule that encodes the CDR region of an anti-CCR5 monoclonal antibody PA14, PA8, PA9, PA10, PA11

and PA12. The Examiner stated that the sub-combination has separate utility such as to detect the antibodies.

The Examiner therefore stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. The Examiner additionally stated that because these inventions are distinct for the reasons given above and the search required for each listed Group will not overlap, restriction for examination purposes as indicated is proper.

The Examiner further stated that applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. The Examiner stated that any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

The Examiner then stated that applicants' election with traverse of Group VI in Paper No. 8 is acknowledged. The Examiner stated that the traversal is on the grounds that the restriction is improper because Groups V-VII are not independent from one another and that a restriction can only [be] proper if the separated inventions are independent AND distinct from one another, while quoting

from MPEP §802 and 35 U.S.C. §121. The Examiner stated that this is not found persuasive. The Examiner stated that applicants are taking the teachings of the MPEP out of context. The Examiner stated that MPEP §806 states that a restriction is proper if the inventions are able to support separate patents and they are either independent (citing MPEP §806.04 - 806.04(i)) **or** distinct (citing MPEP §806.05 - 806.05(i)). (Emphasis in original). The Examiner stated that, "In the instant case, each Groups can support a separate patent and that are distinct from one another for each groups are directed [to] Nucleotide sequences encoding different proteins [that] are structurally distinct chemical compounds and are unrelated to one another." The Examiner therefore stated that these sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. The Examiner stated that, absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 USC 121 and 37 C.F.R. 1.141 *et seq.* The Examiner stated that the requirement is still deemed proper and is therefore made FINAL unless applicants admit that the Groups are obvious variants of each other.

In response to the present restriction and/or election requirement among claims 87-88, 91-95 and 98-101, applicants' undersigned attorney, on behalf of applicants, hereby elects, with traverse, to prosecute the claims of the Examiner's Group I, i.e., Claims 87-88, 91-95 and 98-

101 drawn to a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 monoclonal antibody designated as PA14, PA8, PA9, PA10, PA11 and [sic. "or"] PA12, classified in class 536, subclass 23.53.

Applicants respectfully submit that the present claims under examination are related as genus and species, rather than combination and sub-combination, and thus should all be examined together in this application. It is in fact apparent from the Examiner's own statements in the paragraph bridging pps. 3-4 of the Office Action purporting to support her contention that the claims are not directed to a combination and sub-combination wherein, in attempting to demonstrate that the claims are distinct one from another, the Examiner stated:

> In the instant case, the combination as claimed does not require the particulars of the sub-combination as claimed because not all sub-combination, nucleic acid molecules that are drawn to different antibodies are necessary to produce the combination, a nucleic acid molecule that encodes the CDR region of an anti-CCR5 monoclonal antibody PA14, PA8, PA9, PA10, PA11 AND PA12. [Emphasis on "AND" in original, underlining provided by applicants].

The Examiner thus contends that the "combination" as recited, e.g., in claim 87, is a nucleic acid molecule capable of encoding the CDR regions of all of PA14, PA8, PA9, PA10, PA11 **AND** PA12. This is not, however, what is recited in claim 87. In contrast to the Examiner's description of the alleged "combination", claim 87 recites a nucleic acid molecule encoding one or more CDR regions of an anti-chemokine receptor 5 (CCR5) monoclonal antibody

designated PA14, monoclonal antibody designated PA8, monoclonal antibody designated PA9, monoclonal antibody designated PA10, monoclonal antibody designated PA11, **OR** monoclonal antibody designated PA12.

Rather than being drawn to a combination, claim 87 is directed to nucleic acid molecules encoding one or more CDR regions of an anti-CCR5 antibody designated, **in the alternative**, PA14 or PA8 or PA9 or PA10 or PA11 or PA12. Claim 87 therefore does not recite a combination, but rather a genus as explained below. Thus the requirement for restriction issued by the Examiner on the basis that applicants' claims are directed to a combination and sub-combination is unsupported and the Examiner is therefore respectfully requested to reconsider and withdraw the requirement.

The present claims are more appropriately described as encompassing a genus, together with a reasonable number of species of that genus. The species are:

1) a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 antibody designated as PA14;
2) a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 antibody designated as PA8;
3) a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 antibody designated as PA9;
4) a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 antibody designated as PA10;
5) a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 antibody designated as PA11; and
6) a nucleic acid molecule that encodes one or more CDR regions of an anti-CCR5 antibody designated as PA12,

whereas the genus, as recited in, e.g., claim 87, is an isolated nucleic acid molecule encoding one or more CDR regions of an anti-chemokine receptor 5 (CCR5) monoclonal antibody designated PA14, or a monoclonal antibody designated PA8, or a monoclonal antibody designated PA9, or a monoclonal antibody designated PA10, or a monoclonal antibody designated PA11, or a monoclonal antibody designated PA12.

M.P.E.P. §806.04(d) defines what a generic claim is. As stated therein:

It is not possible to define a generic claim with that precision existing in the case of a geometrical term. In general, a generic claim should include no material element additional to those recited in the species claims, and must comprehend within its confines the organization covered within each of the species.

For the purpose of obtaining claims to more than one species in the same case, the generic claim can not include limitations not present in each of the added species claims. Otherwise stated, the claims to the species which can be included in a case in addition to a single species must contain all of the limitations of the generic claim.

Once a claim that is determined to be generic is allowed, all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim will ordinarily be obviously allowable in view of the allowance of the generic claim, since the additional species will depend thereon or otherwise include all of the limitations thereof.

The M.P.E.P. further states, in §806.04(h):

Where generic claims are allowed in a national application, applicant may claim in the *same application* additional

species as provided by 37 C.F.R. 1.141.

37 C.F.R. §1.141(a) reverts back to the quotation above from M.P.E.P. §806.04(d) in light of its statement that:

. . . [m]ore than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§1.75) or otherwise include all the limitations of the generic claim.

Applicants contend that claim 87 meets the requirements of M.P.E.P. §806.04(d) and thus is clearly generic. It includes no material element additional to those recited in the species claims and comprehends within its confines the organization covered in each of the species, i.e., a nucleic acid molecule that encodes one or more CDR regions of a (particular) anti-CCR5 monoclonal antibody, i.e., not all of monoclonal antibodies PA14, PA8, PA9, PA10, PA11 **AND** PA12. Moreover, as additionally required under M.P.E.P. §806.04(d) the generic claim does not include limitations not present in the species claims.

Based upon such determination that the subject claim is generic applicants are entitled, under the provisions of 37 C.F.R. §1.141, to claim *in the same application*, a *reasonable number* of species of the invention. Applicants are herein claiming six specific anti-CCR5 monoclonal antibodies (PA14, PA8, PA9, PA10, PA11 and PA12) which have been isolated and identified in the development of their invention. It is further asserted that six species are a

"reasonable number" of species under the present circumstances.

The Examiner is therefore respectfully requested to reconsider and withdraw the restriction requirement among claims 87-88, 91-95 and 98-101 and to examine all of these claims together in this application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants undersigned attorney invites the Examiner to telephone either of them at the number provided below.

No fee, other than the enclosed $210.00 fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fees are due, authorization is hereby given to charge the required amount of such fee(s) to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450
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